keted in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.".

Federal Register, publication.

SEC. 9. GOOD MANUFACTURING PRACTICES.

21 USC 343 note.

Section 402 (21 U.S.C. 342), as amended by section 4, is amended by adding at the end the following:

"(g)(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring when necessary expiration date labeling, issued by the Secretary under subparagraph (2).

"(2) *The* Secretary may by regulation

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ogy. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5, United States Code.".

SEC. 10. CONFORMING AMENDMENTS.

TT c & SECTION 201.—The last sentence of section 201(g)(l) (21 U.S.C. 321(g)(l)) is amended to read as follows: "A food or dietary ^SPle^ent for which a claim> subject to sections 403(r)(l)(B) and 403(r)(3), or sections 403(r)(l)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and ^SL1^g statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.".

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

"(u) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section

(c) SECTION 403.—Section 403 (21 U.S.C. 343), as amended by section 7, is amended by adding after paragraph (s) the following:

"A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.".

SEC. 11. WITHDRAWAL OF THE REGULATIONS AND NOTICE.

The advance notice of proposed rulemaking concerning dietary f^fr^n^1^118116*1 m the Federal Register of June 18, 1993 (58 FR 33690-33700) is null and void and of no force or effect insofar as it applies to dietary supplements. The Secretary of Health and Human Services shall publish a notice in the Federal Register to revoke the item declared to be null and void and of no force or effect under subsection (a).

SEC. 12. COMMISSION ON DIETARY SUPPLEMENT LABELS.

There shall be established as an executive branch a commission to be known as the Commission on Dietary Supplement Labels (hereinafter in this section referred to as the "Commission").